

DEPARTMENT OF THE NAVY BUREAU OF MEDICINE AND SURGERY 2300 E STREET NW WASHINGTON DC 20372-5300

IN REPLY REFER TO 6530/2.5
Ser M3F2/0060
4 Jun 03

From: Chief, Bureau of Medicine and Surgery

Subj: REVISED GUIDELINES FOR WEST NILE VIRUS (WNV) SCREENING, DEFERRAL, TESTING, AND LOOKBACK

Ref: (a) ASBPO BPL 03-07 of 2 Jun 03

- (b) FDA Guidance for Industry, Revised Recommendations for the Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection, May 2003
- (c) BUMED ltr 6530/2.5 Ser M3F2/0085 of 27 Nov 02

Encl: (1) Navy Blood Program Office Policy on Blood Donor Screening, Deferral, and Lookback for West Nile Virus (WNV), 4 Jun 03

- (2) NBPO Donor Center Personnel Instructions for Direct Oral Question (DOQ) for West Nile Virus (WNV), 4 Jun 03
- (3) Acknowledgement and Implementation Form
- 1. The Navy Blood Program Office (NBPO) provides procedural guidance and operational policies for Navy and Marine Corps facilities responsible for collection, storage, and/or transfusion of blood products. The NBPO is revising the guidelines for blood donor screening, deferral, testing, and lookback for WNV that is consistent with both Armed Services Blood Program Office (ASBPO) policy and guidance from the Food and Drug Administration (FDA) in references (a) and (b). Reference (c) provided interim guidance to prevent the transfusion transmission of WNV and is rescinded upon implementation of this guidance. Nucleic Acid Testing (NAT) for WNV will be implemented under an investigational new drug (IND) protocol and will be required on or about July 01, 2003.
- 2. Navy Blood Donor Centers (BDC) are to implement the Navy Blood Program Office Policy on Blood Donor Screening, Deferral, Testing, and Lookback for WNV (enclosure (1)) which meets the FDA guideline. Allogeneic and autologous donors are to receive the WNV Information Sheet (enclosure 1, Attachment A) with other Donor Information Literature. During the interview, the screener will ask, verbatim, the WNV-direct oral question in enclosure (2) and will document the donor's response according to established procedures in Section V of the Blood Donation Record (DD Form 572).

Subj: REVISED GUIDELINES FOR WEST NILE VIRUS (WNV) SCREENING, DEFERRAL, TESTING, AND LOOKBACK

- 3. All Navy facilities must follow the donor and patient lookback policy for WNV when a donor tests positive for WNV or WNV related post donation information is received, or when a recipient with a recent diagnosis of WNV who received a blood transfusion or organ donation is identified (enclosure (1)). Report cases of WNV infection to the Navy Environmental Health Center, Norfolk, Virginia (757) 953-0700.
- 4. A Biological Product Deviation report will be required if post-donation information related to WNV is received in cases where product retrieval and quarantine and/or notification of recipients of prior or subsequent collections from the donor occurs. If a suspect donation results in fatality in a transfusion recipient, a report of the fatality must be submitted to the FDA.
- 5. Each BDC must incorporate this change into appropriate standard operating procedures (SOP), validate, and train staff to insure the policy is adequately implemented as soon as possible but not later than 13 Jun 03. The incorporation of this policy on WNV into your facility specific SOPs will not require additional changes to the blood donor medical conditions and medication lists. All navy facilities are to return enclosure (3) to BUMED-M3F2 by 13 Jun 03 to indicate receipt of the policy and dissemination to management staff and appropriate healthcare providers.
- 6. Points of contact for this matter are Ms. Jan Sigmon, QA Manager, or myself at DSN 762-3434 or (202) 762-3434.

M. C. LIBBY
By direction

Distribution:
NATNAVMEDCEN Bethesda MD
NAVHOSP Camp Lejeune NC
NAVHOSP Great Lakes IL
NAVMEDCEN Portsmouth VA

NAVMEDCEN San Diego CA USNAVHOSP Okinawa JA USNAVHOSP Guam

Copy to: Cont'd on next page

Subj: REVISED GUIDELINES FOR WEST NILE VIRUS (WNV) SCREENING, DEFERRAL, TESTING, AND LOOKBACK

Copy to: Cont'd NAVHOSP Bremerton WA NAVHOSP Camp Pendleton CA NAVHOSP Charleston SC NAVHOSP Cherry Point NC NAVHOSP Jacksonville FL NAVHOSP Lemoore CA NAVHOSP Oak Harbor WA NAVHOSP Pensacola FL ASBPO Washington DC CDR USAMEDCOM FT Sam Houston TX COMLANTFLT Norfolk VA HQ USAF Bolling AFB DC USNS MERCY NEHC Norfolk VA

USNAVHOSP Roosevelt Roads PR USNAVHOSP ROOSEVEIT ROADS POUSNAVHOSP Naples IT
USNAVHOSP Rota SP
USNAVHOSP Sigonella IT
USNAVHOSP Yokosuka JA
USNAVHOSP Guantanamo Bay CU
USNAVHOSP Keflavik IC
CNO (N931) Washington DC
COMPACFLT Pearl Harbor HI COMPACFLT Pearl Harbor HI COMUSNAVEUR Naples IT USPACOM JBPO Okinawa JA USNS COMFORT

Purpose

Establish revised policy regarding blood donor screening, deferral and lookback for West Nile Virus. This policy applies to collections of Whole Blood, blood components (including recovered plasma), Source Plasma and Source Leukocytes collected from allogeneic and autologous donors intended either for use in transfusion or for further manufacture into injectable and non-injectable products. Update applicable Standardized Operating Procedures (SOP) in accordance with (IAW) this policy.

Background

WNV is primarily transmitted in birds through mosquito bites. Humans are incidental hosts. WNV is associated with human encephalitis and meningitis. In 2002, a major outbreak of WNV was detected in many parts of the United States. The number of human cases of WNV illness in 2002 totaled 4161 and 277 deaths were reported as of March 12, 2003. The 2002 WNV epidemic involved the first documented cases of WNV transmission through blood transfusion, organ transplantation, intrauterine infection, and possibly breastfeeding. Since 80% of persons infected with WNV do not develop any illness and remain asymptomatic, even while transiently viremic, careful predonation screening and WNV testing of blood and plasma donors for WNV is necessary to reduce the risk of WNV infection through blood transfusion.

Definitions

The following definitions apply to WNV in this policy:

Term	Definition
Symptoms of WNV Infection	 Measured fever [temperature greater than 100.4 °F (38°C)] AND One or more flu-like symptom suggestive of WNV infection (e.g. headache, eye pain, body aches, generalized weakness, new generalized skin rash, swollen lymph nodes) Additional information available on CDC website: http://www.cdc.gov/ncidod/dvbid/westnile/clinical guidance.htm OR www.cdc.gov/ncidod/dvbid/westnile/city_states.htm

Definitions (continued)

Term	Definition	
Measured Fever	• Temperature greater than 100.4 °F (38°C)	
Medical Diagnosis of WNV Infection	 Current or recent illness compatible with WNV AND Positive test for WNV IgM antibodies 	
Suspect Donation(s)	The collection(s) from which an infected recipient received a blood component	
Donors At Risk of Transmitting WNV	 Measured fever with headache or with other WNV symptoms within 7 days prior to and 14 days after donation Recent diagnosis of WNV infection AND donated blood within 14 days prior to and 28 days after onset of symptoms Recent confirmed positive test for WNV NAT Determined to be potentially associated with a case of transfusion transmitted WNV 	
Donors Potentially Associated with Transfusion Transmitted WNV Patients Potentially Associated with Transfusion	 A recipient is later diagnosed with WNV AND The recipient received blood components from the donor within 28 days before the onset of symptoms in the recipient. Diagnosis of WNV infection AND Received blood transfusions or organs within 28 days preceding onset of symptoms 	
Transmitted WNV		

Donor Screening and Deferral

Perform the following 8 steps to screen the donor for possible WNV infection.

Step	Action	
1	Provide each allogeneic and autologous donor with the WNV	
information contained in Attachment A.		

Continued on next page

2

Donor Screening and Deferral (continued)

Step	Action		
2	ask the donor if they read and understood the WNV information		
	provided to them.		
	If the donor	Then	
	Understands the WNV	Continue	
	information provided		
	Does NOT understand the	Explain and answer any	
	WNV information provided	questions for the donor	
3		IV screening question: "In the past	
		lained, measured fever of greater	
	than 100.4 °F (38°C) associate		
4	Determine whether or not the do	nor is deferred for possible WNV:	
	If the donor	Then the donor is	
	Answers NO to the WNV	NOT deferred for WNV infection	
	screening question		
	Answers YES to the WNV	Deferred for 28 days from the	
	screening question	date of interview	
	Has a history of or reports	Deferred temporarily until re-	
	a confirmed positive test	instated in accordance with the	
	for WNV NAT on any	WNV NAT testing protocol and	
	previous donation	Service-specific SOPs. The donor	
		may NOT be re-instated any	
		sooner than 28 days after the	
		date of the confirmed positive	
		donation.	
	Had a recent diagnosis of	Deferred for 28 days from the	
	WNV infection	onset of illness or 14 days after	
		the condition is considered to be	
		resolved, whichever date is later.	

Donor Screening and Deferral (continued)

Step	Action		
	If the donor	Then the donor is	
	Has been notified that a previous	Deferred for 28 days	
	donation is potentially associated	from the date of the	
	with transfusion transmitted WNV	implicated donation	
	infection		
		C 1C '11 XY/NXY	
5	Document whether or not the donor is d	eferred for possible WNV	
	infection IAW facility-specific SOPs.	200 : DD00 m	
6	If donor is deferred, enter deferral in DI	BSS using DBSS Temporary	
	Deferral Code 906.		
7	Encourage donors to report any information		
	becomes known to them after their dona		
	• Unreported measured fever of greater than 100.4 °F (38°C)		
	associated with headache, occurring within 7 days prior to donation.		
	• Unexplained measured fever of greater than 100.4 °F (38°C)		
	associated with headache or associated with other symptoms		
	suggestive of WNV infection, occurri	ng within 14 days after	
	donation.		
	Notification that one of their blood donations tested confirmed		
	positive for WNV NAT.		
	Recent diagnosis of WNV infection.		
	• Notification that one of their donations is suspected of being		
	potentially associated with transfusion transmitted WNV infection		
	in a transfusion recipient.		

WNV Testing

When WNV test kits are available for use, perform the following 5 steps to test all homologous and autologous donors for possible WNV infection.

NOTE: Tests will be performed using the nucleic acid testing (NAT) methodology, will initially be performed under investigational procedures, and will subsequently be performed using a licensed test when available.

WNV Testing (continued)

Step	Action		
1	Test the donation for WNV in accordance with NAT testing protocols and facility-specific SOPs.		
2	Determine if the donor is confirm with NAT testing protocols.	ed positive for WNV in accordance	
3	Use the following criteria for production based on the results of WNV NA	duct management and donor deferral Γ.	
	If the donor Then		
	Tests negative for WNV NAT	Make blood components available and do not defer donor	
	Tests confirmed positive for WNV NAT	Quarantine and destroy all components Temporarily defer donor until re-instated in accordance with WNV NAT testing protocols and facility-specific SOPs. The donor may NOT be re-instated any sooner than 28 days after the date of the confirmed positive donation.	
4	If donor is deferred, document donor deferral for WNV NAT in accordance with facility-specific SOPs.		
5	If donor is deferred, enter deferral in DBSS using DBSS Temporary Deferral Code 906.		

Lookback and Post Donation Information

Perform the following 7 steps for donor and patient lookback when a donor tests confirmed positive for WNV NAT or WNV related post donation information (PDI) is received.

NOTE: Quarantine and retrieval of previously collected components applies to collections of Whole Blood and blood components intended for transfusion, as well as <u>unpooled</u> Source plasma, recovered plasma, and Source Leukocytes intended for further manufacturing into injectable and non-injectable products. <u>Quarantine and retrieval is not recommended for those products that have been pooled for fractionation.</u>

Step	Action	
1	Perform the following steps for product identification/retrieval:	
	If PDI is received about	Then promptly identify and locate all in-date products
	 Donors with mild symptoms of upper respiratory infection unassociated with fever OR Donors with only mosquito bites 	NOT required or recommended.
	Donors with an unexplained measured fever of >100.4 °F (>38°C) associated with headache or associated with other symptoms suggestive of WNV infection, occurring within 7 days prior to or 14 days after donation.	Collected within 14 days prior to and 28 days after the onset of symptoms in donor.
	Donors testing confirmed positive for WNV NAT on a blood donation.	Collected within 14 days prior to and 28 days after the date of the initial positive blood donation.

Lookback and Post Donation Information (continued)

Step	Action		
	Donors with a recent	Collected within 14	• •
	diagnosis of WNV infecti	n. prior to and 28 day onset of illness in t	
	170		
	If PDI is received about	Then promptly id locate all in-date p	• ,
	Patients with recent diagn of WNV infection who	that were transfuse	d to the
	received blood transfusion or organ donations within	he previous donations	from the
	28 days preceding the ons of WNV symptoms.	that were collected days prior to and 2 after the "suspect" donation(s).	within 28 8 days
	Donors suspected of being potentially associated with transfusion transmitted Winfection in a recipient	Associated with "s donation and all pr donations collected days prior to and 2 after the "suspect"	evious 1 within 28 8 days
2	Perform the following steps for product management, consignee notification, and recipient notification:		consignee
	If products are/were	Then	-11 1-11
	Available	Quarantine and destroy a products. Document disp	
	Shipped	Notify consignee(s) to q and destroy all products. Document notification.	uarantine
	Destroyed	Document disposition.	

Lookback and Post Donation Information (continued)

Step	Action	
	Transfused AND donor	Identify and Notify prior recipients
	illness is a medical	of the potential WNV transfusion
	diagnosis of WNV	risk. (Relevant units are those
		dating from 14 days prior through
		28 days after the onset of illness of
		the donor).
	If products are/were	Then
	Transfused but donor	Do NOT notify prior recipients of
	illness is NOT medical	blood components collected from
	diagnosis of WNV	that donor.
	Transfused and	Do NOT notify prior recipients of
	potentially associated	blood components collected from
	with transmission of	that donor
	WNV to a transfusion	
	recipient, but NOT	
	confirmed through	
	epidemiological	
	investigation	
	Transfused and the	Identify and notify prior recipients
	likely source of	of blood components collected
	transmission of WNV	from that donor of the potential
	to a transfusion	WNV transfusion risk. (Relevant
	recipient, AND	units are those dating from 28 days
	confirmed through	prior to 28 days after the date of
	epidemiological	the donation that is implicated in
	investigation	transmission of WNV).

Lookback and Post Donation Information (continued)

3	IAW Command and Navy Environmental Health Center (NEHC) procedures, notify local public health personnel and Navy Blood Program Offices of donors diagnosed with or potentially infectious for WNV and of any transfusion recipients potentially at risk for WNV transfusion transmitted infection.		
4		ols for shipment of patient samples	
	for further study (757) 953-070	·	
		ooratory samples for CDC can be incidod/dvbid/westnile/clinical	
	guidance.htm	network avoid westitte einea	
	60		
	If samples are	Then	
	Needed for further testing	Ship IAW NEHC or NBPO	
	directions		
	NOT needed	Discard IAW local policy	
Step	Action		
5 tcp 5	Document PDI and lookback IAW facility -specific SOPs.		
6	If donor is deferred, enter donor deferral in DBSS using temporary		
	deferral code 906. (See Donor Screening and Deferral section of		
	the document, for appropriate donor deferral criteria)		
7		ation (BPD) reports, IAW Navy	
	Blood Program QA SOPs, in instances of post-donation		
	information related to WNV in cases where:		
		I mi ppp :	
	A suspect blood product		
	Was retrieved and	Required, contact Navy	
	quarantined as a result of a WNV PDI report	Blood Program Office	
ı			
	Was transfired and resulted	Required contact Navv	
	Was transfused and resulted in notification of a		
	Was transfused and resulted in notification of a transfusion recipient	Required, contact Navy Blood Program Office	

Lookback and Post Donation Information (continued)

Step	Action	
_	Was transfused and resulted in the fatality of a transfusion recipient	Required, contact Navy Blood Program Office
	NOT distributed	NOT required

CDC Reporting Requirements

To assist in identification of other possible cases of WNV infection potentially associated with transfusion, the FDA also requires that:

If	And	Then
Patient is diagnosed with WNV infection	Patient has received blood transfusion or organs within 28 days preceding onset of WNV symptoms	 Possible transfusion transmission of WNV should be reported to the CDC through local public health authorities. AND Serum or tissue samples should be retained for later studies
Donor is diagnosed with WNV infection	Donor had onset of WNV symptoms within 14 days of blood or organ donation	Possible transfusion transmission of WNV should be reported to the CDC through local public health authorities via NEHC

Continued on next page

Enclosure 1

Labeling of Products

Quarantined products that were distributed for research or intended for further manufacturing into Non-Injectable products, must be labeled consistent with recommended labeling described below as applicable:

- "Biohazard" OR
- "Collected from a donor determined to be at risk for West Nile Virus" **OR**
- "Collected from a donor positive for evidence of infection with West Nile Virus" **OR**
- "For laboratory research use only" **OR**
- "Intended only for further manufacturing into non-injectable products"

11 Enclosure 1

Donor Information About West Nile Virus (WNV)

What is WNV?

West Nile Virus infection has been associated with human encephalitis and meningitis. Throughout 2001 and 2002, WNV spread to about half of the US. In 2002, over 4000 cases of WNV illness and 277 deaths were reported. 99% of human cases in 2002 occurred between 2 July and 30 October.

How can I get WNV?

WNV is a mosquito borne virus that is primarily transmitted in birds through mosquito bites. WNV can also be transmitted from birds to humans through mosquito bites.

Can WNV be passed by blood transfusion?

Yes. The 2002 WNV epidemic involved the first documented cases of WNV transmission through blood transfusion, organ transplantation, from mothers to infants during pregnancy, and possibly during breastfeeding.

Can I donate blood today?

The Food and Drug Administration has recommended that donors who have a risk of being infected with WNV do not donate blood for a short interval.

You may NOT donate blood if you	You must wait	
Had an unexplained measured fever of greater than	At least 28 days from today's attempted	
100.4 °F (38°C) associated with a headache within	donation date	
the last 7 days OR		
Have been recently diagnosed with WNV infection	At least 28 days from the first day of	
OR	WNV symptoms or until 14 days after	
	the WNV illness is resolved	
Have been notified that one of your blood donations	Until you are notified that you are	
tested positive for WNV	eligible to donate again, but at least 28	
	days after the date of the confirmed	
	positive donation.	
Have been notified that one of your previous blood	At least 28 days after the date of that	
donations is the potential cause of WNV infection in	previous donation.	
a patient that has been transfused with your blood		

After you donate blood!

Thank for ensuring the safety of the blood supply! As long as you are well and remain well, you need not take any other measures. However you should notify the blood donor center and see your doctor if:

- In the 14 days after your donation, you become ill with a fever of 100.4 °F or higher **AND** have cold-flu symptoms **OR**
- You later find out that you meet any of the other restrictions above.

DONOR CENTER PERSONNEL INSTRUCTIONS FOR DIRECT ORAL QUESTION (DOQ) FOR WEST NILE VIRUS (WNV)

This WNV-DOQ must be asked out loud to **EACH** donor at **EACH** donation. Documentation of the screener's initials in Section V of the DD 572, *Test, AUG 1998 Beside a printed statement, stamp, or overlay: "WNV-DOQ"* confirms the WNV- DOQ was asked.

"IN THE PAST WEEK, HAVE YOU HAD A FEVER WITH HEADACHE?"

- Donors who answer "Yes" to the question are deferred for 28 days (4 weeks) from the date of the interview.
- Donors who answer "No" to the question are not deferred.

ACKNOWLEDGMENT OF RECEIPT AND

IMPLEMENTATION		
_	LINES FOR WEST NILE VI	RUS (WNV) SCREENING,
Identifier: BUMED ltr 0060	6539/2.4 Ser M3F2/	Date: 04 Jun 03
The Navy Blood Program must monitor receipt and change control at each of the Surgeon General's facility identified under the Food and Drug Administration's License 635. The Navy Blood Program's policy for above subject matter was received and implemented as indicated below.		
Note: SIGN AND RETAIN ORIGINAL FOR YOUR FILES. COPY AND FAX THIS FORM AS SOON AS POSSIBLE, BUT NO LATER THAN 13 Jun 03 TO:		
CHIEF, BUREAU OF MEDICINE AND SURGERY NAVY BLOOD PROGRAM (M2F3) 2300 E STREET, NW WASHINGTON, DC 20372-5300 FAX (202) 762-0930		
Facility:		
Address:		
Base/City:		
State:		Zip Code:
Date Received:	Date Changed:	Date of Complete Implemented:
<pre>Implemented (print):</pre>	Signature:	Title:
Comments:		
BELOW FOR NAVY BLOOD TRACKING ONLY		
Date Received at M2F	'3:	Date entered:
Database enter by:		
Comments:		